and Toxoids Efficacy Review). 50 FR 51002 (Dec. 13, 1985).

In March 2003, six plaintiffs, known as John and Jane Doe 1 through 6, filed suit in the United States District Court for the District of Columbia (the Court) seeking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense, and to declare AVA an investigational drug when used for protection against inhalation anthrax. On December 22, 2003, the Court issued a preliminary injunction barring inoculations under the AVIP in the absence of informed consent or a Presidential waiver of the informed consent requirement.

In the **Federal Register** of January 5, 2004 (69 FR 255), FDA published a final rule and final order in response to the report and recommendations of the independent advisory panel that reviewed the safety and effectiveness data pertaining to AVA. Following FDA's issuance of the final rule and final order, the Court lifted the preliminary injunction on January 7, 2004, except as it applied to the six Doe plaintiffs.

On October 27, 2004, the Court issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. The Court also enjoined operation of the AVIP for inoculation using AVA to prevent inhalation anthrax. On December 29, 2004, FDA reopened the comment period on the Bacterial Vaccine and Toxoids Efficacy Review for 90 days. As a result of the Court's October 27, 2004, order, the use of AVA for the prevention of inhalation anthrax under the AVIP is deemed an unapproved use of an approved product.

II. Determination of the Department of Defense

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb–3(b)(1)(B), the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax.

By letter dated December 22, 2004, the Assistant Secretary of Defense for Health Affairs (Assistant Secretary) requested that the Food and Drug Administration issue an Emergency Use Authorization for the use of AVA for protection against inhalation anthrax. The letter of the Assistant Secretary states that the Deputy Secretary of Defense has assigned authority from the Secretary of Defense to make the statutory determination under section 564(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act.

III. Declaration of the Secretary of Health and Human Services

On December 10, 2004, the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. Pursuant to 21 U.S.C. 360bbb–3(b) and on the basis of such determination, I hereby declare an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed subject to the conditions described in the authorization issued under 21 U.S.C. 360bbb(a). Notice of the authorization issued under 21 U.S.C. 360bbb(a) is provided elsewhere in this issue of the **Federal Register**.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–2027 Filed 1–31–05; 11:39 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Grants for Battered Women's Shelters.

OMB No.: New collection.

Description: This information collection is authorized under Title III of the Child Abuse Amendments of 1984, Public Law 98–457, as amended. In response to the program announcement, the respondents must submit information about their services program and their eligibility. Information that is collected is used to award grants under the Grants for Battered Women's Shelters program.

Respondents: State agencies administering the Family Violence Prevention and Services program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State FVPSA Agencies	53	1	6	318
Estimated Total Annual Burden Hours				318

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: January 26, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–1895 Filed 2–1–05; 8:45 am]

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